PATENT
Customer No. 76,392
Attorney Docket No. SP-01-US-DIV-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Campbell et al.	)	Group Art Unit: 1632
	)	
Application No.: 09/225,233	)	Examiner: D. Crouch
	)	
Filed: January 4, 1999	)	Confirmation No.: 2711
	)	
For: QUIESCENT CELL POPULATIONS FOR NUCLEAR TRANSFER	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF UNDER 37 C.F.R § 41.41

Pursuant to 37 C.F.R § 41.41, Appellant submits this Reply Brief in response to the January 4, 2010, Examiner's Answer. This Reply Brief is due on March 4, 2010, and is timely filed.

The Examiner errs in construing the claims as product-by-process claims

The Examiner contends that Appellant's claims are product-by-process claims. (Examiner's Answer at 15-18.) However, Appellant's claims are not product-by-process claims.

In contrast to the Examiner's allegation on page 15, last paragraph, Appellant's claims do not use the term "clone" as an adjective, but rather use the term "clone" as a noun. Nor do Appellant's claims use the verb forms "cloning" or "cloned." Appellant's use of the term "clone" as a noun disproves any attempt to read a particular method of cloning into the claims. Thus, the Examiner's attempt to read the phrase "cloning by somatic cell nuclear transfer" into the claims (*id.* at 18, first full paragraph) violates a basic canon of claim construction. That is, it is improper to read a limitation from the specification into a claim. *See, e.g., Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1248, 48 USPQ2d 1117, 1120 (Fed. Cir. 1998).

The customary use of the term "clone" does not require any particular process for making the clone. Appellant points out that the Board previously understood the term "clone" to mean "a genetic copy of a living thing." (January 30, 2008, Board Decision at 3, first full ¶.) This definition is consistent with Appellant's use of the term and does not imply any particular process for making the clone. Consequently, the term "clone" in Appellant's claims does not convert

them into product-by-process claims. Accordingly, Appellant's claims 155-159 and 164 are properly construed as pure product claims, and not product-by-process claims.

The Examiner errs in concluding that Appellant's clone is a product of nature

The Examiner contends that Appellant's clone is not new because it is a product of nature. (Examiner's Answer at 22-23, bridging ¶.) As the Board previously found, mammals do not naturally reproduce by cloning. (January 30, 2008, Board Decision at 14, first full paragraph.) Accordingly, Appellant's clone cannot be a product of nature. Nature simply does not make clones of mammals. Since Appellant's clone must be made by man, it is statutory subject matter under 35 U.S.C. § 101. *See Diamond v. Chakrabarty*, 447 U. S. 303, 308 (1980).

The Examiner's contention that "there is no unique genetic composition to mammals" is unsupported and in error

In the Examiner's Answer, the Examiner alleges that that, "there is no unique genetic composition to mammals." (Examiner's Answer at 31.) Similarly, the Examiner alleges that "mammals produced by sexual reproduction can have the same genetic complement as shown by the art" (*id.* at 16), "sexual reproduction does not necessarily give mammals with distinct genome" (*id.* at 34-35, bridging ¶), and "sexually produced mammals have the same genetic code as indicated by

DNA fragment (RFLP) analysis" (*id.* at 38, first full ¶). The Examiner's allegations are unsupported and are in error.

Appellant's clone is a genetic copy of a non-embryonic donor mammal. Mammals produced by sexual reproduction are not genetic copies of any non-embryonic donor mammal. As recognized by the Board in its prior Decision, "A comparison of the chromosomal DNA of the claimed clones with that of the donor would be expected to show virtual identity. In contrast, a comparison of the DNA of sexually reproduced horses and rats of the references with that of either one of the parents would be expected to show only 50% identity." (January 30, 2008, Board Decision at 27-28, bridging ¶.) The Examiner's allegations otherwise are in error.

The Examiner relies on the publications of Flisikowski et al. and Koelher et al. to support her position. Flisikowski looked at a single 215 bp fragment of a single gene in 8 bovines and found 3 different patterns of fragments sizes. (At 150, Fig.1) This result does not support the Examiner's allegation that there is no unique genetic composition to mammals. If Flisikowski et al. only looked at 215 bases of the total chromosomal DNA and found 3 different patterns of fragments sizes in 8 bovines, it is readily apparent that looking at an entire chromosomal DNA of millions of bases could uncover a multitude of additional differences in nucleotide sequence. Thus, the Examiner's conclusion that the chromosomal DNA

of millions of bases from any two bovines is identical based on an analysis of only 215 bases of a single gene is unfounded.

Similarly, Koelher et al. did not even look at total chromosomal DNA, but only looked at specific sequences in mitochondrial DNA. Thus, the Examiner's conclusion that the chromosomal DNA of millions of bases from any two bovines is identical based on an analysis of only mitochondrial DNA is unfounded.

The Examiner improperly disregards that Appellant's claims require two mammals, one of which is a time-delayed genetic copy of the other

Because Appellant's clone is a clone of a pre-existing, non-embryonic mammal, Appellant's claims require two animals, namely, a pre-existing, non-embryonic, donor mammal and a clone of that donor mammal. This pair of animals has a special relationship in that one of the mammals is a clone of the other pre-existing mammal. The requirement for two animals with this relationship is a structural difference between Appellant's claims and the prior art mammals. The Examiner improperly disregards this difference.

None of the cited references describe a pre-existing, non-embryonic, donor mammal and a clone of that donor mammal. Thus, the prior art lacks this limitation of Appellant's claims. A rejection for anticipation under 35 U.S.C § 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. *See, e.g., In re Paulsen*, 30 F.3d 1475, 1478-79, 31

USPQ2d 1671, 1673 (Fed. Cir. 1994). Since the prior art is missing this limitation of Appellant's claims, the cited prior art cannot anticipate them.

While the Examiner admits that Appellant's clones "may have uncontrolled phenotypic differences" from other mammals of the same species, the Examiner focuses on what exact physical or structural features distinguish them. (Examiner's Answer at 28,-29, bridging paragraph.) Anticipation under 35 U.S.C § 102 can be found only when the reference discloses exactly what is claimed; where there are differences between the reference disclosure and the claim, the rejection must be based on 35 U.S.C § 103, which takes differences into account. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 USPQ 773, 777 (Fed. Cir. 1985). Since the Examiner admits that Appellant's clone has differences from other mammals of the same species, Appellant's clone cannot be anticipated.

The Examiner further contends that the specification lacks a method to distinguish a clone from any other mammal of the same species. (Examiner's Answer at 30, first full ¶.) However, Appellant's specification need not teach what is well known in the art. *See, e.g., Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534, 3 USPQ2d 1737, 1743 (Fed. Cir. 1991).

The differences between Appellant's clones and the clones of the cited references also preclude a finding of obviousness of Appellant's claims. Appellant's claims require a pre-existing, non-embryonic, donor mammal and a

clone of that donor mammal. Such a pair of mammals could not have been expected from the prior art. Rather, prior to Appellant's invention, it was not considered to be possible to produce a clone of a non-embryonic mammal. What was thought to be impossible cannot be obvious. *See, e.g., In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966)("Obviousness cannot be predicated on what is unknown."). Thus, Appellant's clone could not have been obvious at the time the application was filed.

Respectfully submitted,

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Dated: February 15, 2010

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